

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

Date: March 18, 1999 0452 '99 MAR 19 09:39

To: Dockets Management Branch (HFA-305)

From: Ted Sherwood
Management Analyst
Office of Generic Drugs

Subject: Presentation Regarding Human Generic Drugs to Docket
90S-0308

This memorandum forwards overheads of a presentation to the Dockets Management Branch for inclusion in Docket 90S-0308. The following is information on the presentation for the Docket records:

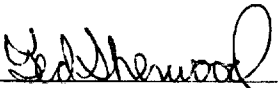
Title of Presentation: FDA Stability Guidance Update

Presented for: 1999 PDA Spring Conference

Date Presented: March 2, 1999

Presented by: Kenneth J. Furnkranz

Number of Pages: 13



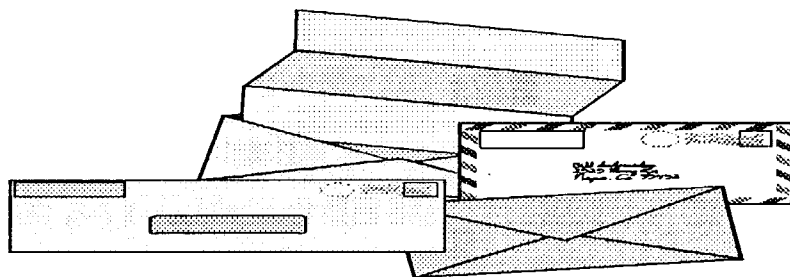
Attachment

90S-0308

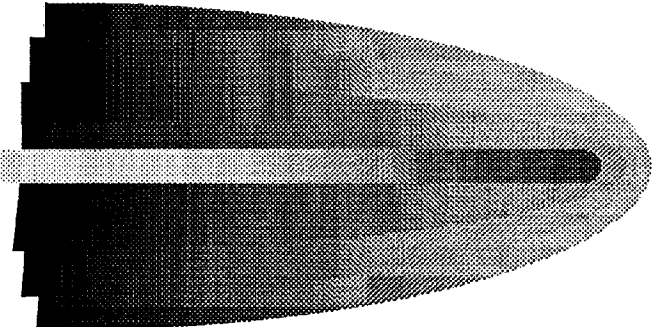
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A stylized illustration of a sword. The hilt is long and features a dense, cross-hatched texture. The blade is dark and tapers to a point. The entire illustration is rendered in a monochromatic, high-contrast style.

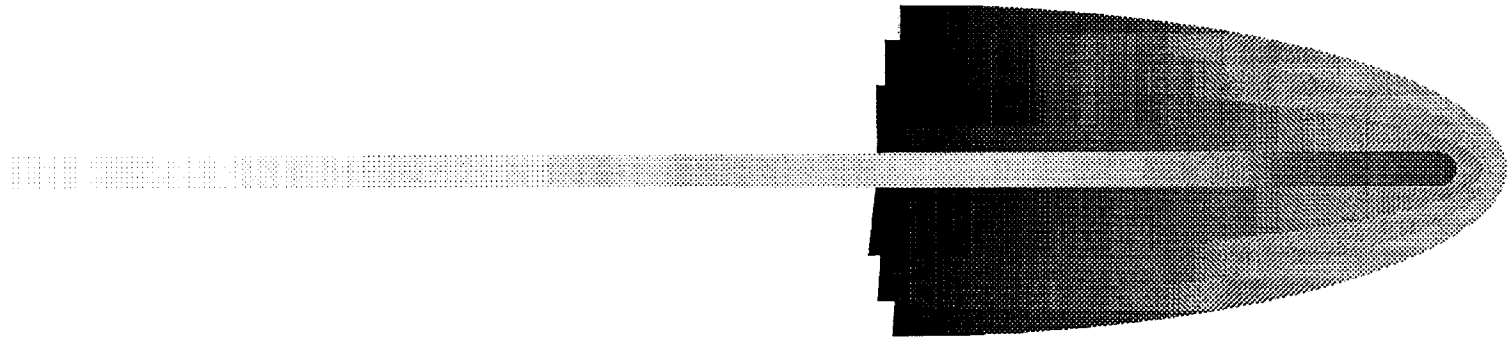
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TimeLine

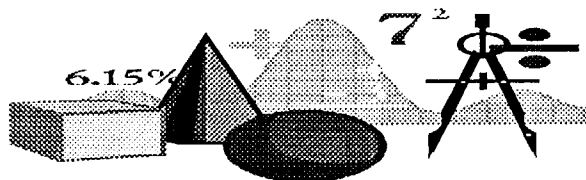
- 
- 6/8/98 Draft Stability Guidance Issued
 - 12/8/98 Comment Period Ended
 - 1/15/98 Last of Comments received
 - 4/1/99 Complete Data Base Development
 - 6 mos.? Incorporate Comments (as appropriate)
 - ? Issue Guidance

Guidance Comments



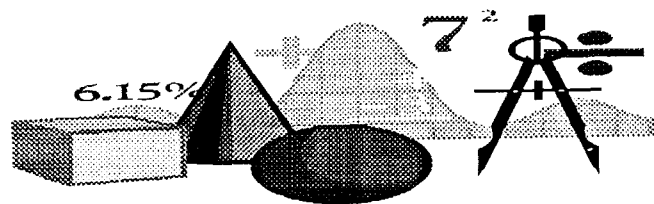
- 60 Entities (Individuals, Groups, Firms, Trade Organizations) provided comments to date.
- Over 575 pages of comments.
- Over 3000 individual comments.
- All Aspects of Guidance covered.





Global Issues

- Remove ICH Guideline Text
 - Q1A: New Drug Substances and Products
 - Q1B: Photostability
 - Q1C: New Dosage Forms
 - Q5C: Biotechnology Products



Global Issues

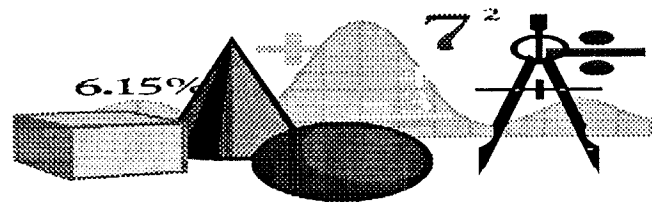
- Eliminate Duplication of SUPACs

Process

Site Change

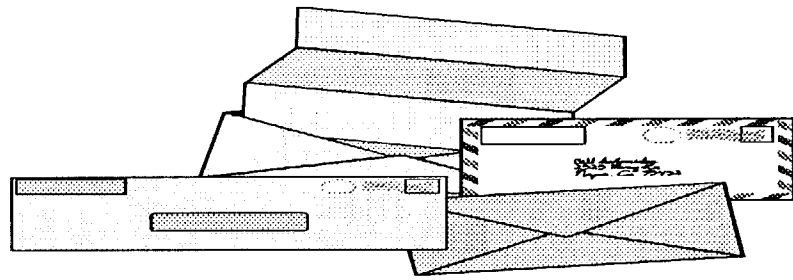
Formulation

Batch Size



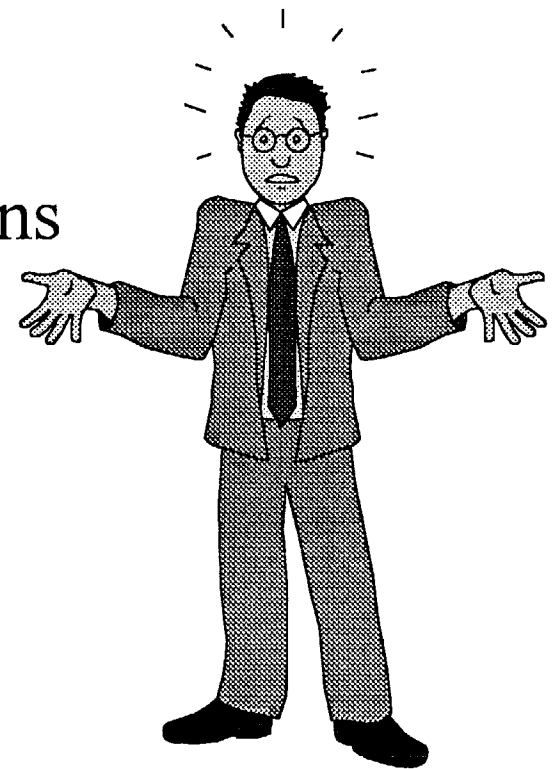
Global Issues

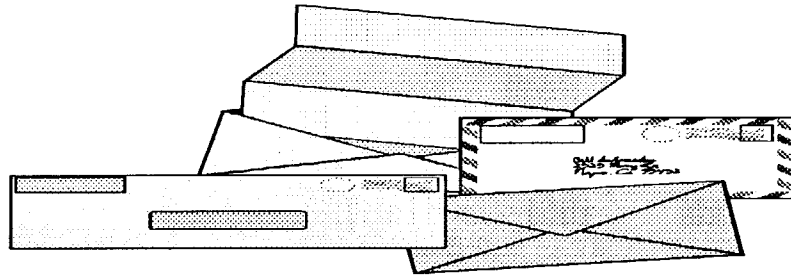
- Remove/Revise MKT Information
 - GMP Issue ?
- Remove ANDA Section
 - Make a separate guidance



Important Topics

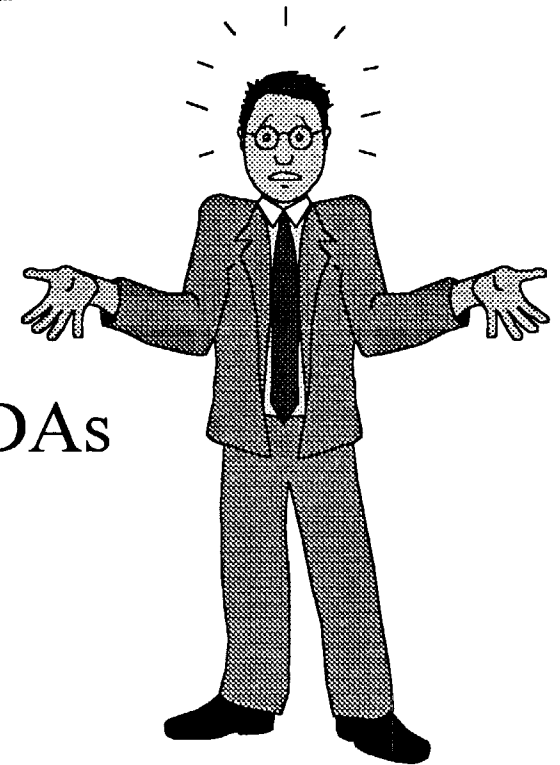
- Uniform Storage Statements
 - Develop consistency with USP
 - More reflective of actual conditions
- Switchover to ICH Conditions
 - Voluntary
 - Mechanism (Plan A vs Plan B)



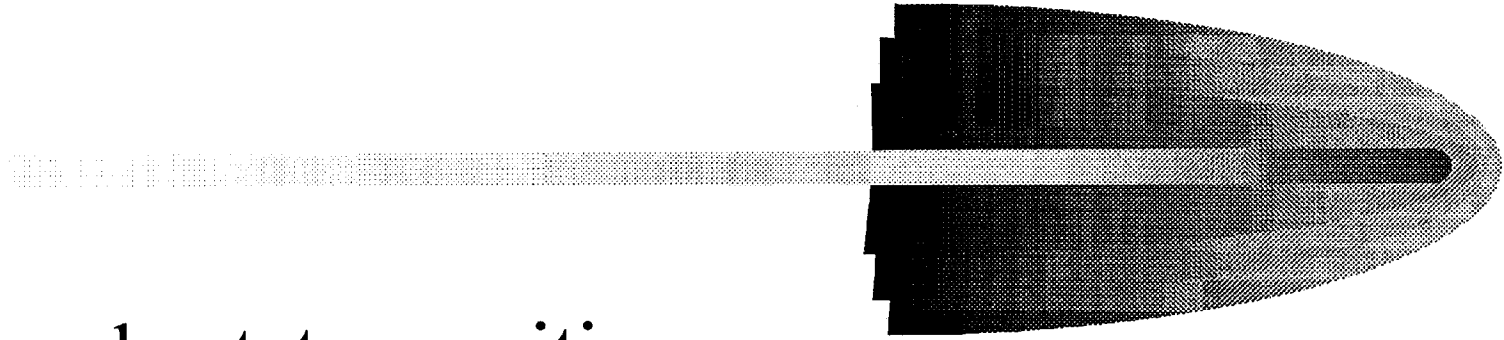


Important Topics

- ANDA Section
 - ICH Conditions
 - Data Package
 - Differences between NDAs & ANDAs

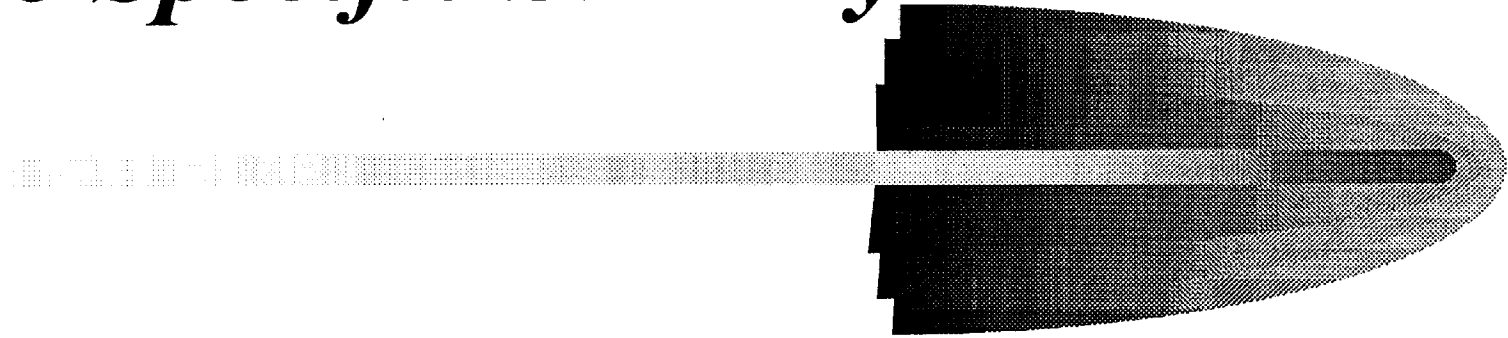


Site Specific Stability



- Clearly states position.
 - Consistent (but restrictive) position
- Areas of Contention
 - Data Filing Requirements (DS & DP)
 - Time of Filing of Application
 - During Review Process
 - Post-approval?
 - Data package

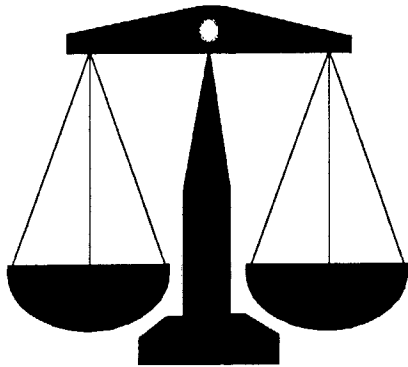
Site Specific Stability Comments



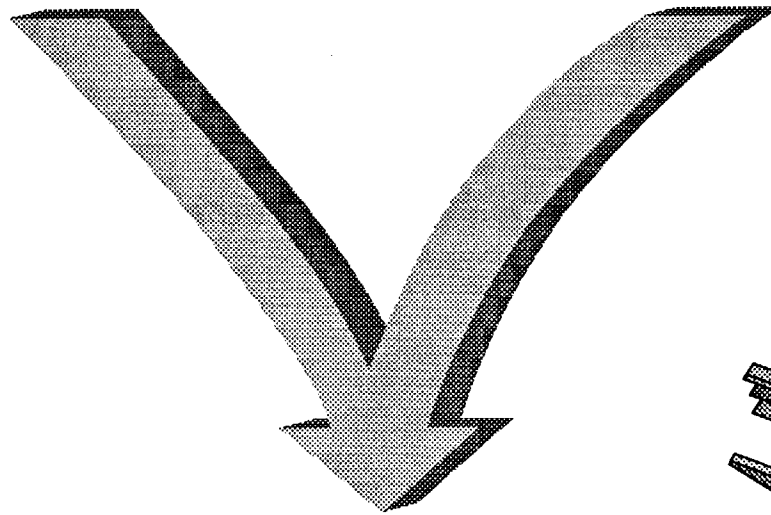
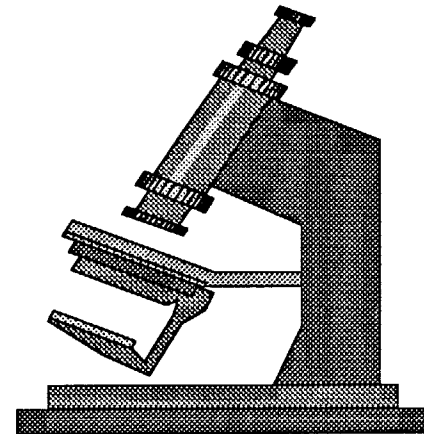
- 60 Entities Provided Comments
- 25 Entities commented on SSS
 - Regulatory (8)
 - Scientific (13)
 - Logistical / Economic (12)
 - Technical (2)

Site Specific Stability

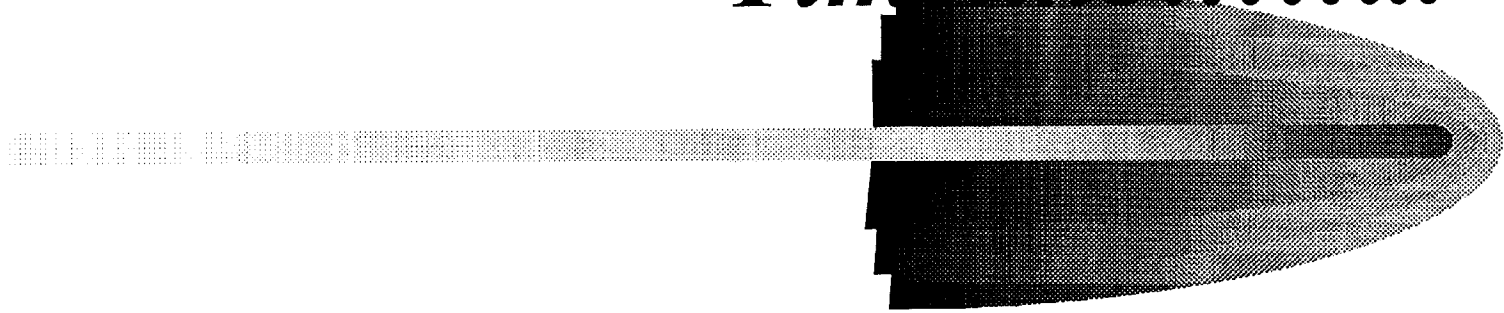
- Appropriate under current policy, legislation, and guidance?



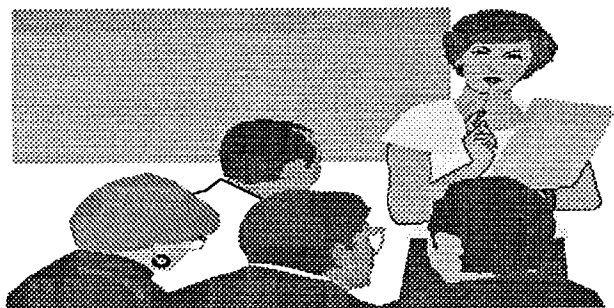
- Scientifically Justified?



Site Specific Stability Timeline.....



- Current Thinking Presented in 6/98 Draft
- July 21, 1998 Meeting on SSS
- Guidance Comments on SSS
- 2/3/99 Meeting: Academic Experts on SSS
- Rework of SSS Section of Stability Guidance
- 3/31/99 Open Meeting on SSS



Site Specific Stability Open Meeting.....

WHO: FDA, Industry, Academia, Individuals.
Groups, etc.

WHEN: March 31, 1999
9:00 AM - 3:00 PM (tentative)

WHERE: Advisors and Consultants Conf. Room
5630 Fishers Lane (tentative)

WHY: Comment on FDA's SSS Position.